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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,651	01/16/2001	Stefan Kiesewetter	206579	2260

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EXAMINER

SCHULTZ, JAMES

ART UNIT PAPER NUMBER

1635

DATE MAILED: 01/07/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/646,651

Applicant(s)

KIESEWETTER ET AL.

Examiner

J. Douglas Schultz

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 8-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 8-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 02 November 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

The Office does not have a signed declaration for inventors Bridgitte Koch-Pelster and Eckehard Kuhn.

Drawings

New corrected drawings are required in this application because the margins are too small. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Response to Arguments

Applicants' traverse of the restriction requirement of the Office action mailed September 19, 2002 is noted. Applicants' arguments filed October 29, 2002 have been fully considered but they are not persuasive. Applicants indicate that the Office failed to meet the requirements of a proper restriction requirement. Applicant points out that a proper restriction must demonstrate that the inventions are independent and distinct, and further, the examiner must indicate that a

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search and examination would constitute a serious burden on the examiner. Applicant then correctly states that the Office action did not so much as allege that a serious burden would be imposed on the examiner to search the inventions of groups I and II.

In response, Applicants are reminded that the present application was filed under 35 U.S.C. 371, where the PCT-based standard of restriction is applied. Accordingly, the restriction requirement of the previous office action was directed to showing that a lack of unity existed among the inventions. See M.P.E.P §1893.03(d). As such, there is no requirement incumbent upon the Office to show that the groups are independent and distinct, or that a serious burden would be imposed on the examiner under 35 U.S.C. §121, but rather to show that a lack of unity exists. Thus, Applicant's arguments are misdirected. The multiple sequences of the application as originally filed are subject to restriction based on a lack of unity guidelines as outlined in the previous Office action. For these reasons the restriction requirement is deemed proper, and the restriction requirement is made **FINAL**.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 10 provides for the use of a ribonucleotide protein (RNP), but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process

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applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant is also referred to the Guidelines on Written Description published at FR 66(4) 1099-1111 (January 5, 2001) (also available at www.uspto.gov). The following passage is particularly relevant.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between structure and function structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. A "representative

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number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within a genus, one must describe a sufficient number of species to reflect the variation within the genus. What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. In an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.

Claim 8 is directed to a RNP ternary complex containing a protein from the family of S100 proteins, an RNA of SEQ ID NO:3 and a copper metal ion.

The language of claim 8 broadly embraces such ternary complexes comprising *any* member of the family of S100 proteins. The specification as filed identifies only one actual polypeptide member of said family, in this case by sequence. The specification fails to identify any other members of said family by any means, including by name, relevant structural characteristics, sequences, or important domains or regions of said sequences or proteins. Since the language of claim 8 clearly encompasses all members of the family of S100 proteins, Applicants would need to have described a representative number of S100 protein family members as outlined in the Guidelines on Written Description above, which would include a representative sample of the alleles and variants from species that express said protein, and from proteins that retain a function within reasonable functional similarity of said protein family in order to claim possession of the entire genus.

A person of skill in the art would not view the sequence of one S100 family member alone as adequately describing a representative sample of the broad genus of family members. Thus, the person of skill in the art would be unable to envision the ternary complex of claim 8

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comprising any member of the S100 family of proteins, and would thus conclude that applicant was not in possession of the invention as stated. A person of skill in the art could not begin to envision how said invention would work using any sequence of S100 protein other than that described. As a result, the specification does not provide adequate written description for ternary complexes comprising S100 family members that are heretofore undescribed.

Claims 8 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for RNP complexes comprising the amino acid sequence of SEQ ID NO: 1 and the nucleic acid sequence of SEQ ID NO: 3, does not reasonably provide enablement for RNP complexes comprising any amino acid sequence that is part of the S100 family of proteins and SEQ ID NO: 3. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim 8 is directed to a RNP ternary complex containing a protein from the family of S100 proteins, an RNA of SEQ ID NO:3, and a copper metal ion.

The specification as filed does not provide any guidance or examples that would enable a skilled artisan to make or use the instantly claimed RNP that comprises any protein of the S100 family. Thus, although the specification prophetically considers general methodologies of making a RNP comprising any protein from the S100 family, such a disclosure would not be

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considered enabling since predicting the interaction of a specific amino acid sequence with a RNA molecule of specific sequence is highly unpredictable. The factors listed below have been considered in the analysis of enablement:

- (A) The breadth of the claims;
- (B) The nature of the invention;
- (C) The state of the prior art;
- (D) The level of one of ordinary skill;
- (E) The level of predictability in the art;
- (F) The amount of direction provided by the inventor;
- (G) The existence of working examples; and
- (H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Said claims are drawn very broadly to include RNP's that comprise any amino acid sequence so long as it belongs to the S100 protein family. As outlined above, the specification only discloses the use of the amino acid sequence of SEQ ID NO: 1. All remaining members of the S100 family are undescribed in the specification. The state of the art of predicting amino acid sequence interactions with nucleic acid sequences is highly unpredictable due to the exceedingly complex three-dimensional chemical structure that is unique to each individual amino acid sequence, and the resulting myriad possibilities of hydrophobic/philic interactions that may form with the nucleic acid sequence. Because each remaining S100 family member that is heretofore undescribed would necessarily possess its own unique tertiary structure, and consequently its unique binding characteristics with a given nucleic acid sequence, one of ordinary skill in the art could not possibly predict how such undescribed S100 amino acid sequences might interact with the nucleic acid sequence of SEQ ID NO: 3, or whether there would be an interaction at all.

Furthermore, because there are no working examples of any compounds that comprise more than the RNP of SEQ ID NOS: 1 and 3, the quantity of experimentation required to practice the invention as claimed would require the *de novo* characterization of each S100 family member with the nucleic acid sequence of SEQ ID NO: 3. Since the specification fails to provide any guidance for making such compounds beyond that comprising SEQ ID NOS: 1 and 3, one of skill in the art would have been unable to practice the invention without engaging in undue trial and error experimentation as presented in the specification over the scope claimed.

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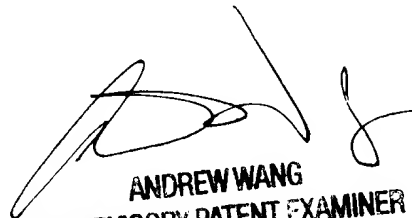
Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Douglas Schultz whose telephone number is 703-308-9355.

The examiner can normally be reached on 8:00-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 703-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

James Douglas Schultz, PhD
December 27, 2002


ANDREW WANG
SUPERVISORY PATENT EXAMINER
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